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| 09/533,493 | 03/23/2000 | Oscar Jimenez | 20037 | 1061 |

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EXAMINER

THISSELL, JEREMY

ART UNIT PAPER NUMBER

3763

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/533,493

Applicant(s)

JIMENEZ, OSCAR

Examiner

Jeremy T. Thisell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

New Matter

The amendment filed 8 September 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has added limitations to the claims that specify materials that are hardness memory materials and specifically NOT shape memory materials.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant has added negative limitations to the claims, requiring materials that are not shape memory materials. However, in the specification the material of choice, and the only example given with any specificity is a shape memory material by Mitsubishi called MM-3500 (aka RememomerTM). The Bley reference discussed below in rejections reproduced from the previous office action, teaches use of a similar Mitsubishi material, MM-3501. These materials are shape memory materials.

There may be some confusion about this due to the operating modality of the materials because it is different from the most common shape memory materials used for catheters. The most common shape memory materials used for catheters are those which are soft at cooler temperatures for easy insertion into the body, then once the body's temperatures warms up the catheter, the catheter material returns to its "memory" shape, which is specific to the anatomy of the patient where it is used. For

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example, many cardiac catheters have a specific shape to reach particular locations in and around the heart and surrounding vessels.

The difference with the Mitsubishi materials is that they are soft at warmer temperatures and hard at softer temperatures. The memory shape is that of the soft, warmer state rather than the hard state. However, the real utility of these materials lies in the fact that if deformed while in the soft state, and held under stress, cooling of the material back to its hard state will “freeze” the new shape formed under stress. Then, the memory comes into play when the material is warmed back up. When warmed, the material “relaxes” and returns to its natural (remembered) shape. Bley has found use for this material by creating a catheter that is hard and stiff, yet the tip softens as it is being inserted into the body. Thus the catheter shaft remains stiff enough to push it into the body, but soft at the tip to avoid damage to the vessels. Bley Abstract.

Applicant’s specification, page 3, lines 23-31 specifies that the material may be MM-3500. The scope of the disclosure only reaches as far as to say that similar thermoresponsive materials may be used for this application. There is no specific mention that a material may (or should) be used that is a hardness memory but not a shape memory material. The only exemplary material given is, in fact, a shape memory material. See the cited Chinese reference with English diagrams and charts (www.puchina.com. . .) Page 4 of this reference shows in Table 2, entitled “Physical Properties of shape memory polyurethane.” Then the chart shows properties for four different Mitsubishi materials, including MM-3500.

In *Ex parte Grasselli*, 231 USPQ 393, 396 (1983), it was held that a rejection under 35 U.S.C. 112 first paragraph is proper when the specification contains no enablement for a newly added negative claim limitation. In *Ex parte Parks*, 30 USPQ2D 1234, 1236 (1993), the Board of Patent Appeals and Interferences refined this application of 35 USC 112 stating that "We are not unmindful of the decision in *Ex Parte Grasselli*. . ." but holding that "In the situation before us, it cannot be said that the originally-filed disclosure would not have conveyed to one having ordinary skill in the art that appellants had possession of the concept of conducting the decomposition step generating nitric acid in the absence of a catalyst." The Board went on to say that in the specification of the application, "Throughout the discussion, which would seem to cry out for a catalyst if one were used, no mention is made of a catalyst."

Here, Applicant's argument might be that although hardness memory materials were discussed, there was no mention of shape memory materials or their properties. However, the only exemplary material given by applicant was, in fact, a shape memory material. Applicant's new claim language incorporating a negative limitation with respect to the material not being a shape memory material is specific and narrow. The original disclosure is vague and broad. This specific and narrow subject matter is not encompassed and supported by the original disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Newly added claim limitations that the material is NOT a shape memory material is not supported in the original disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Tovey (US 5,445,140).

Tovey teaches all the claimed subject matter including a catheter with a shape memory tip as claimed (abstract; and col. 3, lines 28 and 44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 12, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140 in view of Bley et al (US 5,762,630) and Schroepfel (US 6,024,764).

Tovey teaches all the claimed subject matter including a catheter with a shape memory tip as claimed (abstract; and col. 3, lines 28 and 44). However, Tovey does not teach the claimed shore D hardnesses or the tubular member having a shape memory outer "jacket", or the braided mesh reinforcing layer. Bley teaches a shape memory catheter wherein the disclosed material comprises polyurethane (col. 4, lines 44-45) is radiopaque (col. 5, line 40), and is taught to have a durometer of 78 D when its temperature is below the glass transition temperature (T_g) and a durometer of 25 D when its temperature is above T_g . Bley teaches that T_g is between 15-35° C, and further states that materials with varying glass transition temperatures may be used (col. 5, lines 17-22).

In addition, Bley teaches that a suitable material is MM-3510 made by Mitsubishi Heavy Industries (col. 4, line 45), which is substantially similar to MM-3500 which is also a polyurethane-based material made by Mitsubishi and is disclosed as the material of choice by applicant on page 3 of their own specification.

It would have been obvious to one of ordinary skill in the art to choose a material with the claimed properties (which are only slightly different than those discussed by Bley), particularly in view of Bley's statement in col. 5, lines 17-22. Further, it would have been obvious to one of ordinary skill in the art to use such a material for the device of Tovey in order to insert the device into the tortuous passageways of the human anatomy.

Schroeppel teaches a shape memory outer jacket and also a braided reinforcement layer for an implantable tubular device such as a catheter. (col. 1, lines 9-10) It would have been obvious to include the jacket and layer of Shroeppel on the device of Tovey as modified by Bley, particularly since part of the catheter in Tovey is already of a shape memory material, in order to facilitate insertion of the device into body lumens as is well-known in the art.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140) in view of Bley et al (US 5,762,630).

See combination of Bley with Tovey discussed above.

Claims 17, 18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140) in view of Schroepel (US 6,024,764).

See combination of Schroepel with Tovey discussed above.

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Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey (US 5,445,140) in view of Bley et al (US 5,762,630) and Schroepel (US 6,024,764) as applied to claim 11, and further in view of Griep (US 5,163,431).

Tovey teaches all the claimed subject matter except for the distal end of the tubular body being tapered. Griep teaches that the distal end of the tubular body is tapered (e.g. element 15; figures 1 and 2. Mating conical sections are a well-known mechanism of interfitting tubular members and would have been an obvious way to connect the tip of Tovey, particularly in view of Tovey's teaching that other methods for securing the sections will be apparent to those skilled in the art (col. 3, lines 14-19).

Response to Arguments

All of applicant's arguments are based on the newly added negative limitations. These limitations are considered new matter and have been addressed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

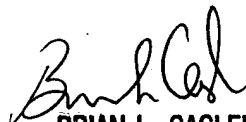
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for all fax communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
October 31, 2003


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